DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Reference Numbers: 95-1530, 95-1531 and 95-1532

Ms. Brigitte W. Knudsen
Statens Seruminstitut
5, Artillerivej
DK-2300 Copenhagen S
DENMARK

JUL 29 1998

Dear Ms. Knudsen:

This letter hereby issues Department of Health and Human Services Biologics License No. 1255 to Statens Seruminstitut, Copenhagen, Denmark, in accordance with the provisions of Section 351(a) of the Public Health Service Act as amended November 21, 1997 (FDAMA; Public Law 105-115), controlling the manufacture and sale of biological products. This license authorizes you to manufacture and import into this country to ship for sale, barter, or exchange those products for which your company has demonstrated compliance with establishment and product standards.

Under this license you are authorized to manufacture the products Tetanus Toxoid Concentrate (For Further Manufacturing Use) and Diphtheria Toxoid Concentrate (For Further Manufacturing Use) to be shipped to North American Vaccine, Inc., in a shared manufacturing arrangement for the manufacture of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP).

The dating period for these products will be 36 months from the date of manufacture. The date of manufacture is defined as the date the bulk purified toxoids are sterile filtered prior to final product release testing. Any requests to extend the dating period for these products beyond 36 months will require the submission of a Supplement to your license application with supporting data. Alternatively, you may submit a stability protocol for prior approval to be used for extension of dating as a Supplement to your license application.

Changes in the manufacturing, testing, packaging or labeling of your Diphtheria and Tetanus Toxoids Concentrates (For Further Manufacturing Use) or in the manufacturing facilities may require the submission of a Supplement to your license application for our review and written approval prior to implementation. Any such changes which may effect the safety, purity and potency of the products when used to prepare DTaP should also be reported simultaneously to North American Vaccine, Inc., the licensed manufacturer of the DTaP.

It is requested that you acknowledge receipt of the enclosed Biologics License to the Director, Division of Vaccines and Related Products Applications, HFM-475.

Sincerely yours,

Steven Masiello
Acting Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

M. Carolyn Hardegree

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
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